DEPARTMENT OF HEALTH & HUMAN SERVICES

New York District

Food & Drug Administration
158-15 Liberty Avenue
Jamaica, NY 11433

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WARNING LETTER

April 6, 2000

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

REF: NYK-2000-59

Facility ID: 219972

Thomas E. Herman, President
Multi-Diagnostic Services, Inc.
73-04 185th Street
Fresh Meadows , New York 11366

Dear Mr. Herman:

Your mobile facility was inspected on March 23, 2000 by a representative of the New York City Bureau of Radiological Health, acting in behalf of the Food and Drug Administration. This inspection revealed a serious regulatory problem involving the mammography at your facility. Under a United States Federal law, the Mammography Quality Standards Act of 1992, your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography. The inspection revealed the following Level 1 finding at your facility.

> ***The system to communicate results is not adequate because there is no system in place to provide timely medical reports. Inspection revealed that mammography reports were not sent to patients without primary health care providers within 30 days of the examination.***

The specific problem noted above appeared on your MQSA Facility Inspection Report which was issued to your facility at the close of the inspection. This problem is identified as Level 1 because it identifies a failure to meet significant MQSA requirements.

Because this condition may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, it represents a violation of the law which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, placing your facility under a Directed Plan of Correction, charging your facility for the cost of on-site monitoring, assessing civil money penalties up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, MQSA standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography.

In addition, your response should address the Level 2 findings that were listed on the inspection report provided at the close of the inspection. The Level 2 findings are:

There is no written procedure for handling consumer complaints;

There is no written procedure for infection control; and

Corrective action for a failing image score (before further exams) was not documented.

It is necessary for you to act on these matters immediately. Please explain to this office in writing within fifteen (15) working days from the date you received this letter:

- The specific steps you have taken to correct the violations noted in this letter including supporting documentation;
- Each step your facility is taking to prevent the recurrence of similar violations; and
- Your system for referring patients who do not have a primary health care provider, when clinically indicated.

Please submit your response to the attention of Lillian C. Aveta, Compliance Officer, U.S. Food and Drug Administration, 158-15 Liberty Avenue, Jamaica, NY 11433.

Finally, you should understand there are many FDA requirements pertaining to mammography. This letter pertains only to findings of our inspection and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, Maryland 21045-6057 (1-800-838-7715), or through the Internet at http://www.fda.gov/cdrh/dmqrp.html.

If you have any questions about mammography facility requirements in general, please feel free to contact Murray L. Kurzman, Radiation Programs Manager, at (516) 921-2035.

Sincerely yours,

Brenda J. Holman
District Director